

PROCEDURES FOR MANAGEMENT OF RADIOACTIVE MATERIALS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook establishes procedures necessary to implement the requirements of the VHA Master Materials License (MML) issued by the Nuclear Regulatory Commission (NRC). The document serves as the basis for the MML in which the VHA assumes much of the oversight for management of radiation safety, which was formerly the sole province of the NRC. ***NOTE:** This Handbook is not applicable to the licensing and operation of the nuclear reactor facility at the Department of Veterans Affairs (VA) Medical Center, Omaha, NE.*

2. SUMMARY OF MAJOR CHANGES: This is a new VHA Handbook that describes the structure and role of the MML oversight program, including the VHA National Radiation Safety Committee (NRSC) and the VHA National Health Physics Program (NHPP). This VHA Handbook contains mandatory procedures for approval and use of radioactive materials in the VHA. It also contains periodic facility auditing requirements and procedures assuring necessary corrective actions are taken.

3. RELATED ISSUES: VHA Directive 1105.1.

4. RESPONSIBLE OFFICE: The Chief Patient Care Services Officer (11) is responsible for the contents of this VHA Handbook. Questions may be referred to the Director, NHPP at (501) 257-1574.

5. RESCISSIONS: None.

6. RECERTIFICATION: This document will be recertified on or before the last working day of March 2005.

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PROCEDURES FOR MANAGEMENT OF RADIOACTIVE MATERIALS

1. PURPOSE AND SCOPE

This Handbook implements the terms and conditions of the Veterans Health Administration (VHA) Master Materials License (MML) agreement with the Nuclear Regulatory Commission (NRC). It sets forth the required administrative and operational procedures for safe management of all radioactive materials regardless of source or method of production and required application of the same standards for acquisition, receipt, storage, distribution, use, transfer, and disposal of byproduct materials regulated by the NRC, i.e., radioactive materials. The functional responsibilities and operational procedures necessary for implementation of the program are described. *NOTE: This Handbook is not applicable to the licensing and operation of the nuclear reactor facility at the Department of Veterans Affairs (VA) Medical Center, Omaha, NE.*

2. REGULATORY AUTHORITIES

a. **Source of Authority.** The Atomic Energy Act (AEA) of 1954 and the Energy Reorganization Act of 1974 (Public Law 93-438) grant to the NRC the authority to regulate Byproduct, Source and Special Nuclear Materials. The NRC Authority extends to the United States, its possessions and territories, and Puerto Rico. Regulations issued by the NRC are found in Title 10 Code of Federal Regulations (CFR) Chapter 1, Parts 0 through 199.

(1) Federal agencies are subject to NRC regulation since neither AEA of 1954, or Public Law 93-438 grant a waiver of sovereign immunity that would permit regulation by any other government entity. Within an Agreement State (see App. A), the state has regulatory authority over non-federal activities conducted on installation property that is not an exclusive Federal jurisdiction.

(2) The NRC delegates to a Federal agency under a MML agreement the authority to perform licensing and oversight functions.

b. **Resource Conservation and Recovery Act (RCRA).** The RCRA gives the Environmental Protection Agency (EPA) authority to regulate disposal of solid wastes that have radioactive materials. *NOTE: Exception: Byproduct, Source and Special Nuclear Material regulated by the NRC under the AEA of 1954.* Solid low-level radioactive wastes (LLRW) include limited quantities of byproduct, source and special nuclear materials. LLRW may contain naturally-occurring and accelerator-produced radioactive materials (NARM) and hazardous wastes. *NOTE: Hazardous wastes are defined in 40 CFR, Chapter 1, Environmental Protection Agency, Part 261, Identification and Listing of Hazardous Waste.* Wastes that contain both NRC-regulated materials and hazardous wastes are designated as mixed LLRW.

(1) The NRC regulates the Byproduct, Source, and Special Nuclear Material constituents.

(2) The EPA regulates hazardous chemical and NARM constituents.

(3) Neither agency has exclusive jurisdiction over Mixed-LLW under current Federal law. Generators of Mixed-LLW must comply with both NRC and EPA regulation.

c. **Clean Air Act.** This law grants the EPA authority over airborne radionuclide emissions from NRC licensed facilities.

(1) Standards controlling effluent releases and radiation doses to exposed persons are found in EPA regulations 10 CFR Part 61, Subpart I, National Emissions Standards for Radionuclide Emissions from Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart H.

(2) Facilities causing airborne radionuclide emissions are subject to both NRC and EPA regulations. Guides for determining compliance with Clean Air Act standards are found in publications EPA 520/1-89-003 and EPA 520/1-89/003.

(3) The Clean Air Act provides for a waiver of sovereign immunity, and VHA facilities may be subject to review and regulation by state and local jurisdictions designated by the EPA.

d. **Other Program Authorities.** The Under Secretary for Health delegation of authority to the National Radiation Safety Committee (NRSC) provides for enforcement actions as a result of VHA facility inspections and the control of acquisition, receipt, distribution, use, transfer, storage, and disposal by VHA organizations of radioactive material including NARM. The NRC confers, through the VHA MML, authority for licensing (use permits), oversight, and internal regulatory enforcement to the responsible VHA organizations while retaining oversight and enforcement authority to assure compliance with applicable regulations.

e. **Occupational Safety and Health Administration (OSHA) Regulation.** OSHA of the Department of Labor (DOL) regulates personnel exposure, uses and conditions of use for sources of radiation not subject to NRC regulation. *NOTE: OSHA regulations are found in 29 CFR 1910.1096.*

f. **Department of Transportation (DOT) Regulation.** Handling and transport procedures and requirements are found in DOT regulations 49 CFR.

3. FUNCTIONAL RESPONSIBILITIES

a. **Under Secretary for Health (10).** The Under Secretary for Health, or designee, acts as the licensed official for regulatory purposes in the conduct of activities under an MML agreement with the NRC, establishes and promulgates VHA policy for control of ionizing radiation uses and hazards, appoints and sustains the VHA NRSC and appoints the NRSC Chairperson.

b. **Chief Officer, Patient Care Services (11).** The Chief Patient Care Services Officer, is appointed as Chairperson of the NRSC. The Chairperson guides the agenda, determines the existence of a quorum, verifies the minutes, summarizes the committee's position regarding decisions, signs all official committee documents, and appoints a temporary replacement chairperson (cannot be the Executive Secretary) in the event of the Chairperson's required absence. At the recommendation of the Committee and as delegated by the Under Secretary for Health, the Chairperson commits VHA resources as necessary to assure that the commitments made in the MML agreement are adequately funded and staffed.

c. **National Health Physics Program (NHPP) Office (115HP)**. The NHPP Office is the operational arm of the NRSC. The office is responsible for:

- (1) Facility radiation safety evaluation and regulatory oversight.
- (2) Assistance to facility-level radiation safety programs.
- (3) Permit application review, approval or disapproval of proposed uses subject to review, and approval by the NRSC.
- (4) Identification and organization of national training priorities for facility-level radiation safety staff.
- (5) Developing policy recommendations for consideration by the NRSC.
- (6) Preparing reports of permit actions, facility evaluations, and as low as reasonably achievable (ALARA) guidance for the NRSC review.
- (7) Acting as the routine point of contact between the NRSC, VHA facilities, NRC, and other regulatory authorities.
- (8) Documenting and maintaining records pertaining to the MML, NRSC actions, VHA permits, and approvals for uses of radioactive materials.
- (9) Establishing conditions for acquiring, receiving, storing, distributing, using, transferring, and disposing of radioactive materials.
- (10) Interpreting this Handbook, license and permit conditions, and, in consultation with the Chairperson, NRSC the ionizing radiation safety policy.
- (11) Assisting in response to all radiological incidents and accidents to ensure safety and compliance with applicable rules and regulations.
- (12) Responding to regulatory agencies concerning program deficiencies and confirming corrective actions.
- (13) Preparing an annual summary of the VHA radioactive materials radiation safety program for NRSC review.
- (14) Initiating procedures and actions to carry out NRSC decisions.
- (15) Suspending authority as required for VHA facilities and individuals to use or supervise the use of radioactive materials in order to protect persons, property, the environment, or to maintain license compliance, reports to and concurrence of the NRSC.
- (16) Obtaining and analyzing program information from facilities as needed to identify trends, anticipate needs, and determine costs and workloads.

d. **VHA NRSC**. The NRSC is the principal organizational element for implementation of the NHPP of the VHA, including any future MML agreement with the NRC. The NRSC:

(1) Provides guidance and information on the radiation control program to the Under Secretary for Health.

(2) Informs the Under Secretary for Health of the level of resources needed to maintain an adequate radiation control program.

(3) Oversees activities of the NHPP in the development, implementation, and maintenance of a radiation control program for all uses of radioactive materials in the VHA.

(a) Prior to an agreement with the NRC establishing an MML, the oversight and control will be in addition to, not in lieu of, NRC license amendments, inspections, and enforcement actions.

(b) Subsequent to an agreement with the NRC establishing an MML, the NRSC, with its actions implemented by the National Radiation Control Program Officer, will be responsible for a program of permitting, inspecting, and enforcing safe uses of ionizing radiation.

(4) Establishes administrative and operational regulation of acquisition, receipt, storage, distribution, use, transfer and disposal of radioactive materials.

(5) Initiates program policy and enforcement actions as delegated to the NRSC by the Under Secretary for Health.

(6) Reviews and enforces or modifies as appropriate, actions of the NHPP.

(7) Reviews and assesses NHPP permitting and inspection staff to assure that the qualifications described in VHA NRSC Standard Operating Procedure (SOP) 04, as derived from NRC Manual Chapter 1246, Inspection Manual Chapter (IMC), are met or exceeded.

(8) Promulgates policy and procedures for implementation by NHPP staff.

(9) Reviews NRC license amendment requests, technical assistance requests, and or permit applications referred by the NHPP Office.

(10) Advises the Under Secretary for Health of the results of NRSC audits and program reviews.

(11) Advises the Under Secretary for Health of non-compliance categorized at Severity Levels I, II, or III as identified in VHA NRSC SOP 03 and as derived from NRC enforcement policy.

(12) Arranges for reviews by, and participates with, independent radiation safety experts as necessary in the annual review and audit of the radiation safety program for assessment of regulatory and policy compliance. ***NOTE: The annual audit shall include a review of NHPP staff inspection and permit review activities and specific corrective actions as necessary.***

(13) Enforces, consistent with NRC allowed or delegated regulatory authority and license conditions, all terms, conditions, and commitments contained in existing NRC licenses and, after an agreement with the NRC, the MML and its application, as defined by MML enforcement procedures.

(14) Meets, as necessary, at the call of the Chairperson, but not less than once in each calendar quarter.

e. **NRSC Chairperson.** The NRSC Chairperson is the Chief Officer, Patient Care Services. At the recommendation of the NRSC and as delegated by the Under Secretary for Health, the Chairperson commits VHA resources as necessary to assure that the commitments made in the MML agreement are adequately funded and staffed.

f. **National Radiation Control Program Officer (RCPO).** The National RCPO serves as the liaison between the NRSC and the NHPP staff and is responsible for administration of the national radiation control program, including the future MML. The National RCPO:

(1) Serves as the Executive Secretary of the NRSC and, in this role:

(a) Informs the Chairperson of staff commitments and resources.

(b) Assists the Chairperson in preparing the agenda.

(c) Advises the committee of current regulations and proposed changes in NRC regulations and policies.

(d) Notifies the NRSC Chairperson of all administrative and technical issues concerning national radiation control program oversight.

(e) Provides the NRSC with quarterly reports on the status of the program.

(f) Assists the NRSC with an annual audit and report, including overall conduct, enforcement actions, program performance results as compared to regulatory requirements, license

commitments, MML commitments, and a review of permitting actions and inspection reports prepared by NHPP staff.

(2) Supervises NHPP Office field personnel performing day-to-day VHA facility license and permit amendment requests, inspections and evaluations, assistance, and training.

(3) Maintains records under the national radiation control program charter and under any future MML agreement.

(4) Initiates procedures to implement policy and program requirements established by the Under Secretary for Health, NRSC, and the NRC.

(5) Serves as the routine point of contact between the VHA and the NRC in matters regarding the MML agreement and its implementation.

(6) After implementation of an MML agreement, provides copies of VHA facility permits and inspection reports to the NRC regional office.

(7) Implements the NRSC's enforcement sanction.

(8) Stops, in coordination with NHPP field personnel, work activities that may pose undue risk or hazard, or that may violate conditions of MML permits or NRC regulations.

(9) Reviews all radiological incidents and accidents to ensure safety and compliance with applicable rules and regulations, and recommends corrective actions to the NRSC.

g. **Veterans Integrated Service Network (VISN) Directors.** The Network Directors are the primary points of contact between VHA Headquarters and the field for a predefined referral-based group of Department of Veterans Affairs (VA) facilities. Relevant functions include the following:

(1) Serves as liaison between the NRSC and their respective medical facilities by CNO membership in NRSC.

(2) Supports corporate decisions of the NRSC, VA directives, and delegations of authority.

(3) Receives copies of all pertinent correspondence and reports sent to facilities by the NRSC or NHPP.

h. **Medical Facility Directors.** The VHA medical facility Director is designated as the responsible official for radioactive material use permit actions authorized by the NRSC and the NHPP Office. The facility directors are responsible for:

(1) Obtaining NRC license or MML permit amendments authorizing all uses of radioactive materials in their facilities.

(2) Obtaining NRC license or MML permit amendments prior to changing uses, facilities, authorized personnel, radiation safety officers, or radiation safety procedures except as authorized in the facility license or permit, this Handbook or in 10 CFR.

(3) Establishing a facility Radiation Safety Committee (RSC) prior to application for a medical use permit (10 CFR Part 35) or a type A broad scope permit (10 CFR 33.11).

(4) Selecting and recommending for approval a qualified RSO responsible for administering the provisions of the radiation safety regulations and the permit.

(5) Ensuring that the VHA facility RSO is responsible for:

(a) Administering regulatory and permit provisions;

(b) Identifying radiation safety problems;

(c) Initiating, recommending, or providing corrective actions; and

(d) Verifying implementation of corrective actions.

(6) Implementing and maintaining corrective actions and enforcing compliance with all terms and commitments in the facility NRC license or MML permit.

(7) Providing the resources to conduct the facility radiation safety program necessary to comply with regulations and permit conditions and to maintain individual and collective radiation exposures ALARA.

(8) Acknowledging and fully endorsing requirements to maintain an open work environment in which all employees are free to raise safety and other concerns and to communicate these appropriately either to the NRSC or directly to NRC without fear of retaliation.

i. **NRSC Membership.** Membership consists of qualified program experts as appointed by the Under Secretary for Health. NRSC members will broadly represent users at facilities, including clinical, research, and radiation safety program activities. Management and administrative members will represent the Office of the Under Secretary for Health and have substantial VHA policy and operations responsibility and experience. NRSC members representing the field must have education, experience, and training appropriate to evaluate radiation safety issues that may influence agency policy. Full voting members include:

(1) Chief Officer, Patient Care Services, Chairperson.

(2) National Radiation Control Program Officer, Executive Secretary.

(3) Chief Network Officer.

(4) Under Secretary for Health's Chief of Staff.

(5) A representative from each of the following offices:

- (a) General Counsel.
- (b) Medical Inspector.
- (c) Research and Development.
- (d) Nuclear Medicine Service.
- (e) Public Health and Environmental Hazards.
- (f) Pathology and Laboratory Medicine Service.
- (g) Radiology Service.
- (h) Nursing Service.
- (6) A representative from radiation oncology.
- (7) Field Clinical Representative.
- (8) Field Research Representative.
- (9) Field Radiation Safety Officer Representative.

j. **Quorum Requirements.** To establish a quorum and conduct business, a two-thirds majority of the voting membership, including the Chairperson and the Executive Secretary or knowledgeable appointed alternates for these two positions, must be present. ***NOTE: Suitable alternates for the Executive Secretary and Chairperson will be a senior NHPP manager and the Executive Assistant, Patient Care Services respectively.***

(1) Committee members who do not attend three consecutive meetings are subject to replacement.

(2) Field representatives may be considered present by teleconference or video-teleconference up-link to ensure membership representation at each meeting.

k. **Facility RSC.** The facility RSC provides expert oversight and evaluation of the facility's uses of radioactive materials. A single RSC at a facility may serve the Committee function for more than one facility permit. The RSC:

(1) Is comprised of members who meet the requirements of 10 CFR Part 35.22 for medical permits.

(2) Includes a management representative, the permit RSO, a representative from Nursing, and a named user for each type of use specified in a non-medical permit.

(3) Meets as necessary at the call of the Chairperson, but not less than once in each calendar

quarter.

(4) Requires a quorum to conduct meeting business consisting of a simple majority, including the RSO and a management representative.

(5) Conducts an annual review of the facility radiation safety program and makes recommendations to correct identified deficiencies and weaknesses.

(6) Approves uses, users, program policy, and program procedures prior to permit application to the NHPP Office or for facility implementation as allowed by the facility permit.

(7) Establishes special requirements, as necessary, for permit uses, including, but not limited to, special monitoring and bioassay.

(8) Reviews on a quarterly basis the RSO's summary reports on radiation exposures and incidents involving radioactive materials.

(9) Ensures that causes of incidents are correctly identified and that adequate corrective actions are taken.

(10) Provides radiation safety program oversight and ensures actions are taken to correct violations or out-of-line situations noted during NHPP or NRC inspections.

1. **Chairperson, Facility RSC.** The Chairperson of the facility RSC is appointed by the facility Director and is qualified by reason of training and experience to manage the radiation safety activities of the Committee. The Chairperson:

(1) Acts for the medical facility director responsible for the permit.

(2) Ensures that the RSC meets as necessary and at least at the required frequencies.

(3) In collaboration with the RSO, conducts the interim business of the RSC.

(4) Prepares and distributes minutes of meetings that include:

(a) Date of meeting;

(b) Members present and absent;

(c) A summary of deliberations and discussions;

(d) A numerical result of all ballots;

(e) Recommended actions specifying the office or person with primary responsibility and status of the action, open or closed;

(f) Approvals granted for individuals, protocols, or other actions and a copy of the credentials and other documents used as the basis for approvals; and

(g) RSO reports and ALARA program reviews.

(5) Ensures that the facility Director, each RSC member and the NHPP Office promptly receive a signed copy of the minutes.

m. **Facility Radiation Safety Officer (RSO).** The facility RSO is the functional and operational arm of the facility RSC for implementing policy, development of procedures and ongoing oversight of local uses of radioactive materials as described in a permit. The RSO:

(1) Is appointed in writing by the medical facility Director.

(2) Investigates overexposures, accidents, spills, losses, thefts, and unauthorized receipt, use, transfer or disposal of radioactive materials, medical misadministrations (see App. A), and other deviations from approved radiation safety practices and implements corrective actions as necessary.

(3) Develops and recommends to the RSC local procedures in writing for acquisition, receipt, storage, inventory, safe use, emergency procedures, surveys, equipment performance checks, disposal, personnel training, and user and facility record keeping requirements.

(4) Briefs medical center management at least once each year on the status of the facility radiation safety program.

(5) Develops and recommends to the RSC investigational action levels for personnel exposures, contamination, and surveys.

(6) Assists the RSC in the performance of its functions, including its annual evaluation of the facility radiation safety program.

(7) Performs periodic on-site evaluations of all activities involving the use of radioactivity in the medical facility including, but not limited to, visits to all areas of use, examination of required records, and evaluations of radiation safety procedures.

(8) Prepares written reports on a quarterly basis for consideration by the RSC that include:

(a) Individual and collective doses of radiation exceeding ALARA investigational levels and the causes and corrective actions, if necessary.

(b) Situations that required special monitoring, i.e., special surveys, bioassay, evaluations for declared pregnant workers.

(c) Incidents that required non-routine response by the RSO, i.e., loss, theft of material, spills, over-exposures, etc., together with corrective actions.

(d) Any other out-of-line conditions.

n. **Teletherapy Physicists.** *NOTE: Teletherapy is the external administration of radiation*

for therapeutic purposes. VHA medical facilities that utilize radioactive materials for radiation treatment in teletherapy devices are required to retain services of a teletherapy physicist who meets the qualification requirements of 10 CFR Part 35.961. The qualifications of a recommended teletherapy physicist are approved by the RSC. The teletherapy physicist is responsible for establishing, supervising, and evaluating a medical physics program that meets all applicable requirements of 10 CFR Part 35 (Subpart I). The teletherapy physicist identifies deficiencies, institutes corrective actions, and maintains records of the evaluation and corrective action programs.

o. **Radioactive Material Users and Workers.** Persons who are granted approval by the NRSC or a facility RSC, if permitted, to use sources of ionizing radiation are responsible for the safe use of these sources by individuals working under their control.

(1) **Approved Users.** An approved user is specifically responsible for:

- (a) Complying with federal regulations and NHPP policy pertaining to uses of radiation.
- (b) Instructing employees under their control regarding the ALARA exposure philosophy, as well as specific instructions pertinent to the procedures to be conducted.
- (c) Ensuring that employees have been instructed and have demonstrated competence in required procedures before being assigned to work involving ionizing radiation.
- (d) Adequate planning of procedures (experiments) to ensure that proper safety precautions are taken including instructions regarding emergencies.
- (e) Requiring personnel to comply with recommendations regarding personnel radiation monitoring, including bioassays.
- (f) Maintaining required survey records, package monitoring records, radionuclide inventories, and radioactive waste disposal and training records.
- (g) Preparing inventories, as required, by the license or permit of radionuclides on hand.
- (h) Ensuring availability of appropriate monitoring and survey instrumentation.
- (i) Maintaining for inspection by employees a copy of the use permit, including conditions of use and a copy of VHA Handbook 1105.1.

(2) **Radiation Workers.** Individual workers performing procedures with radioactive materials, under the direction of an approved user, are responsible for:

- (a) Knowing and understanding pertinent Federal, VHA, and facility regulations and policy.
- (b) Knowing locations where radioactive materials are used or stored.
- (c) Maintaining their radiation exposure ALARA.

- (d) Wearing the recommended personnel radiation monitoring devices and/or following recommended monitoring procedures.
- (e) Surveying of hands, shoes, and clothing for radioactivity and removal of all contamination prior to leaving the work area.
- (f) Using of all recommended protective devices and practices while working with ionizing radiation.
- (g) Reporting radioactive spills, accidents, and unsafe conditions to the RSO.
- (h) Knowing the appropriate response to an emergency involving radioactive material.

4. PROGRAM ELEMENTS

a. **Requirements for Accepting or Using Radioactive Materials.** VHA staff and organizations must obtain through the NHPP Office and the NRSC a valid permit authorizing possession and use of byproduct material except as listed in the following. VHA staff and organizations do not require permits for possession and use of:

- (1) Radionuclides in concentrations exempted by 10 CFR Part 30.14, quantities exempted by 10 CFR Part 30.18
- (2) Radionuclides in concentrations or quantities below limits specified in 10 CFR Parts 30.70, 30.71, and the quantities listed in Appendix B of this Handbook, if not received under an exempt distribution license.
- (3) Items specifically exempted from NRC licensing provisions under:
 - (a) Title 10 CFR Part 30.15, Certain Items Containing Byproduct Material.
 - (b) Title 10 CFR 30.19, Self-luminous Products Containing Tritium, Krypton-85, or Promethium 147.
 - (c) Title 10 CFR Part 30.20, Gas and Aerosol Detectors Containing Byproduct Material.

NOTE: *Generally licensed devices and quantities of radioactive materials in possession of VHA personnel are subject to all receipt, storage, use, inventory, accountability, and disposal requirements. Non-VHA persons or organizations bringing radioactive materials to VHA facilities or using such materials in VHA facilities are not permitted to work within the facility unless they receive prior authorization under the facility's permit procedures.*

b. **Permit Types.** The following permit types may be issued by the NHPP to authorize possession and use of radioactive materials in VHA facilities:

- (1) **General Permit.** A General Permit is issued to VHA organizations wishing to use radioactive materials for in vitro testing in accord with the provisions of 10 CFR Part 31.11, "General License for Use of Byproduct Material for Certain In Vitro Clinical or Laboratory Testing."

(2) **Specific Permit for Medical Use of Byproduct Material.** A specific permit for medical use of byproduct material is issued for uses of radionuclides in humans for diagnostic, therapeutic and human research purposes pursuant to the provisions of 10 CFR Part 35, Medical Use of Byproduct Material. ***NOTE:** An exception: permits authorizing teletherapy uses are issued separately.*

(3) **Specific Permit for Non-Human Byproduct Material Use.** A specific permit for non-human byproduct material use is issued to individual applicants for non-human uses of radioactive materials. The permit explicitly identifies authorized users, uses, and possession limits of specified radioactive materials requested by the applicant. The permit is issued pursuant to the specific licensing authority described in 10 CFR, Part 30.

(4) **Specific Permit of Broad Scope (Type A).** A specific permit of broad scope (Type A) is issued to authorize the use of radioactive materials in types, physical and chemical forms and in quantities explicitly specified in the permit. Users, uses, and radiation safety practices performed under this type of permit are authorized by a facility RSC. Permits are issued according to the provisions of 10 CFR Parts 33.11(a), and 33.13. Uses are limited to non-human laboratory and animal research, except for the two medical permit type subclasses, as follows:

(a) Broad Scope Medical (Type A). This permit is intended to accommodate those organizations having a radioactive material program where the demand is great for a variety of radionuclides and uses. Broad scope medical permittees may authorize use of any byproduct material in medical research activities by anyone in accordance with review and approval procedures and criteria established by the RSC. ***NOTE:** A permittee is one which holds a permit.* Individuals are not specifically named on the permit as users nor are the radionuclides limited to narrow, specific uses. These permits are intended for permittees that cannot operate under a more limited specific permit without disrupting their programs. Only Medical Institution

Broad permittees, as described in following subparagraphs 4b(4)(a) 1. through 4b(4)(a) 6., will maintain or be assigned the medical broad scope program code 02110. **NOTE:** *This code is an internal NRC code describing the type of permit issued.*

1. The permittee has an active medical research program.
2. A medical research program involves human use and may include use of radioactive drugs approved for use by the United States (U.S.) Food and Drug Administration (FDA) or a Radioactive Drug Research Committee (RDRC).
3. The permittee uses an Institutional Review Board (IRB) and/or other appropriate review committees to approve the studies based on ethical considerations, scientific merit, and radiation safety.
4. The permittee uses a broad spectrum of byproduct materials and has demonstrated a need for any byproduct material with atomic numbers between 1 through 83 inclusive.
5. The permittee has sufficient staff, facilities and resources to protect health and safety as determined by NHPP.
6. The permittee's RSC is composed of members who demonstrate sufficient ability by training and experience to name authorized users, and approve facilities and new procedures.

(b) Broad scope authorizations for non-medical research and development with specific medical use of limited scope.

1. Those programs that have medical use authorization in accordance with 10 CFR 35.100, 35.200, and 35.300, and either do not participate in human medical research or participate only in the clinical phases of Investigator's New Drug (IND) studies and do not meet the criteria listed above will be classified as specific medical use permittees of limited scope. These permits may include broad scope authorizations for non-medical research and development pursuant to 10 CFR 30.4, and have either a 03610, 03611, or 03612 as a secondary or primary program code, or limited human research authorization by permit line item. **NOTE:** *These codes reflect internal NRC codes describing the type of permit issued.*

2. Specific Permit of Broad Scope (Type B) is issued to authorize individual applicants to use radioactive materials in types and quantities limited by 10 CFR Part 33.11(b) and in programs conducted under sections of 10 CFR Part 33.14 and 33.17. Users and uses are approved by the facility's qualified RSO.

3. Specific Permit of Broad Scope (Type C) is issued to authorize individual applicants to use radioactive materials in types and quantities limited by 10 CFR Part 33.11(c). The authorized users must meet education, training, and experience requirements and other requirements of 10 CFR Parts 33.15 and 33.17.

4. Specific Source Materials Permit is issued for the use of depleted Uranium as collimator and radiation shielding material in radiation therapy devices. These are routinely issued as a line item on another medical use permit.

5. General Permit for Source Material is issued pursuant to the requirements of 10 CFR 40.22 for limited quantities of source materials such as uranyl nitrate.

NOTE: Needs for other permit types should be discussed with NHPP staff.

(5) **Term of Permits.** Permits are issued for a period of 5 years or as specified in NRC procedures.

NOTE: Type B and C Broad Scope permits are issued only under exceptional circumstances and where there is strong justification for conducting the program without the oversight authority of a local RSC.

c. **Application for Permits and Amendments**

(1) **General Requirements and Policy**

(a) All applications for permits are made in the name of, and through, the VHA facility Director as the responsible permit official.

(b) The facility Director may delegate functional and procedural activities to individuals and organizational elements within the facility, but may not delegate responsibility for regulatory compliance and safety.

(c) Send all correspondence regarding applications to:

National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

NOTE: New applications and amendments have first priority, followed by renewal applications.

(2) **Initial Applications**

(a) NRC forms, regulatory guides, and VHA guidance for the preparation of applications are available from NHPP offices. The application will require a complete description of:

1. The proposed use of radioactive materials,
2. The essential elements of the radiation safety program,
3. Personnel qualifications, and

4. Facilities.

(b) VHA activities, facilities, and organizations planning new or unique applications of radioactive materials need to contact NHPP staff as early as possible to determine the scope of the permit required, and to assess needs for site visits by permit reviewers. Initial applications should be submitted as far in advance of the desired use date as the available information allows, but no later than 90 days before the desired use date.

***NOTE:** Typical uses requiring extended review time include new research or laboratory facilities, clinical programs, and multicurie sealed source irradiators.*

(3) **Renewal Applications.** Renewal applications shall reach NHPP at least 30 days before the permit expiration date. Renewal applications shall fully describe the existing program at renewal time, but not through reference to prior documents. Changes in any uses, personnel, policy, or procedures in the facility renewal must be identified in the cover transmittal letter.

***NOTE:** Program changes take effect upon approval of the renewal application.*

(4) Amendment Requests

(a) Requests to amend the terms and conditions of a current permit or change uses consistent with the scope of the permit type are submitted as amendment requests. These requests may be in the form of a letter that fully describes the changes needed.

(b) Amendment requests should be received by NHPP at least 30 days prior to the effective date of the requested change. Ministerial changes to medical use permits granted under 10 CFR Part 35 may be effected without amendment following the requirements of 10 CFR Part 35.31.

(c) A permit amendment is required prior to:

1. Changing RSOs.

2. Allowing users to possess or use radioactive materials, except when the facility permit specifically authorizes the local RSC to designate users and approve uses.

3. Ordering radioactive materials differing in radionuclide, chemical form, physical form, or in quantities more than the possession limit authorized.

4. Making changes to shielding in any radiation facility that requires shielding in the floors, walls, or ceilings.

5. Receiving and using radioactive materials for clinical procedures authorized in 10 CFR Part 35, but not authorized on the facility permit.

6. Changing teletherapy physicist or allowing an individual not named on the permit to act as the teletherapy physicist.

7. Changing the location of a teletherapy unit or using a teletherapy unit in a way that could increase radiation exposure levels outside of the teletherapy facility.

d. **Inspection Policy.** NHPP inspections of MML permittees will be conducted in accordance with NHPP Inspection Procedures, VHA NRSC SOP 02. These procedures are modeled on NRC inspection procedures. ***NOTE: This subparagraph of the MML Handbook summarizes parts of these procedures of particular interest to MML permittees.***

(1) Inspections of VHA facilities conducting radionuclide programs are a primary responsibility of NHPP. ***NOTE: The purpose of the inspection program is to assess compliance, recognize safety concerns, identify needs for corrective actions, and to assist facility staff in recognizing the causes of deficiencies and implementing remedial safety measures as needed. Routine inspections are unannounced in accordance with the provisions of VHA NRSC SOP 02.***

(2) The NRC will additionally conduct inspections of permitted facilities to sample compliance, but at a reduced frequency compared to individually licensed facilities.

(3) If, during a permit inspection, the NHPP inspector identifies situations that may pose an immediate threat to health and safety, the inspector is authorized to order the immediate suspension of permit activities in the affected area and report the conditions to the NHPP office.

(4) Such actions are immediately reviewed by the RCPO.

(a) **Frequency.**

1. Inspections are conducted at the following frequencies:

a. General Permits: Not scheduled.

b. Limited Scope Byproduct Materials Permits: 3 years.

c. Medical Byproduct Materials Permits: 3 years.

d. Broad Scope Byproduct Materials Permits: 1 year.

2. Programs with significant deficiencies previously identified may be inspected with increased frequency (see VHA NRSC SOP 02). New programs will be inspected within the first several months of operation. Programs with a consistent history of insignificant or no infractions may be inspected at less frequent intervals, subject to the approval of the NRSC (see VHA NRSC SOP 02).

(b) **Content and Criteria.** Inspections examine facility procedures for compliance with all applicable regulations (NRC, EPA, DOT, and OSHA), conditions of use specified in the facility permit that require activities beyond the scope of regulations, and for adherence to NHPP policy. Additionally, activities are assessed in terms of good health physics and radiation hygiene practices, and deficiencies in these areas are addressed as matters of safety concern that must be addressed. Deficiencies, regulatory noncompliance, and health and safety concerns are categorized in accordance with Severity Level examples given in the NRC Enforcement Policy and established enforcement policy defined in NRSC Enforcement Procedures, VHA NRSC SOP 03.

(c) Methods. Inspections consist of administrative and operational evaluation of the facility program. Administrative evaluation consists principally in the examination of records that are required to support mandatory activities. Operational evaluation may consist of staff interviews and observation of required and routine procedures. Interview and observation is intended to assess knowledge of radiation safety principles essential for safe and prudent operations and provides a performance-based appraisal of the program status (see VHA NRSC SOP 02).

(d) Reports. The results of inspections are summarized in a written report prepared by the NHPP inspector and forwarded to the RCPO for NRSC review.

1. Reports are reviewed by NHPP staff and approved by the RCPO. A transmittal letter is prepared that identifies the need (if any) for corrective actions, identification of causes, and requests a full compliance date.

2. Facility Directors, as the responsible agent for permit operations, are required to respond in writing within 30 days to reports in which deficiencies or concerns are identified.

3. The report will contain:

a. Name of facility inspected and dates.

b. Name of facility staff contacted.

c. Description of activities inspected and methods employed.

d. Results, including specific regulatory and condition deficiencies and radiation health and safety concerns.

(e) Distribution of Reports. Reports are sent to the director of the inspected facility with copies to the facility RSO and VISN Director. Copies are maintained by the NHPP field inspector and the NHPP office. An additional copy will be sent to the appropriate NRC regional office.

e. **Enforcement Policy**. Identified program deficiencies that individually or in combination or collectively indicate a potential for significant health and safety threat, or individual incidents that are significant violations may result in enforcement action. The need for such action is determined by the NRSC. The enforcement actions may be preceded by a mandatory meeting of responsible facility staff, with NHPP and permittee staff to determine the extent of deficiencies, causes, and proposed corrective actions. Recommendations for enforcement action can include disciplinary personnel actions, mandatory remedial actions, addition of control measures to permits, suspension of permitted activities or revocation of a facility permit, or repealing an individual's privilege to use or supervise the use of radionuclides. The NRC may initiate enforcement meetings and take enforcement actions against the VHA licensed activities. ***NOTE: Detailed VHA enforcement procedures are described in VHA NRSC SOP 03.***

(1) **Administrative Enforcement**. The NRSC may take administrative enforcement actions including:

- (a) Suspending or revoking authority to possess or use radioactive materials.
 - (b) Adding control measures to permits.
 - (c) Revoking an individual's authority to possess, use or supervise the use of radioactive materials.
- (2) **Disciplinary Enforcement.** Adverse personnel actions and other disciplinary actions are the responsibility of VHA facility or VISN Directors and facility supervisory personnel.

f. **Notices to Workers.** Notices to workers concerning the uses of radionuclides and sources of information at each permit facility are required.

(1) **Posting.** Permittees using radioactive materials must post NRC Form-3, Notice to Employees, and a supplemental notice regarding the availability of a permit and VHA MML documentation according to 10 CFR 19.11, Posting of Notices to Workers.

(2) **Location.** The notices must be visibly posted in areas frequented by all workers using radioactive materials.

(3) **Supplemental Notice.** The following supplemental notice shall be attached to NRC Form-3:

(a) "VHA Radioactive Material Permit No. # facility permit no. # issued under the VHA Nuclear Regulatory Commission Master Materials License No. # master license no. # authorized use of radioactive materials at this location. Contact (name) facility RSO, mail stop, phone # to examine the permit and supporting documents."

(b) The VHA MML, amendments, and the supporting application are maintained by the VHA NHPP Office at the Central Arkansas Veterans Healthcare System, Little Rock, AR. These documents are available for examination by contacting NHPP (115HP), Department of Veterans Affairs, Veterans Health Administration, 2200 Fort Roots Drive, North Little Rock, AR, 72114.

g. **Control of Radioactive Materials**

(1) **Security.** All nonexempt byproduct, source, and NARM materials must be secured from unauthorized removal or access. Materials that are used in unrestricted areas must be under the constant surveillance of an authorized individual when not in storage (see 10 CFR 20 Subpart I, Storage and Control of Licensed Material).

(2) **Accounting.** Facilities are required to have adequate procedures in place to ensure compliance with 10 CFR 30.51, Records of Receipt, Transfer and Disposal, and the permit.

(3) **Inventories.** All radioactive sources and devices including nonexempt quantities must be inventoried as follows:

- (a) For medical permits subject to the requirements of 10 CFR Part 35, inventory all sealed

sources quarterly.

(b) All other permittees inventory all radioactive materials at intervals not exceeding 6 months.

(c) Unsealed sources must be subject to procedures for receipt, use, storage, and disposal that provide for continuous accountability for the disposition of these materials. Accountability procedures must be fully described and submitted with the permit application.

(d) Sealed source inventory records are maintained for 5 years and include the following information:

1. Date of inventory,
2. Source identification (ID),
3. Name of radionuclide and activity,
4. Location, and
5. Signature of RSO certifying the accuracy of the inventory.

h. **Transfer of Radioactive Materials.** Radioactive materials may be transferred subject to the following conditions:

(1) **Authorized Recipients.** Materials may be transferred only to an organization or person authorized to receive the materials under the terms of a VHA permit or an NRC or Agreement State license; a VHA organization with written authorization to receive materials by NHPP; DOE and DOE prime contractors who certify in writing that they are authorized to receive the materials; common and contract carriers; freight forwarders; and warehouse workers for transporting or storing materials subject to 10 CFR 30.13, Carriers, and 10 CFR 40.12, Carriers.

(2) **Verification.** Ensure that the recipient is authorized by obtaining a copy of the recipient's VHA, NRC, or Agreement State license, or obtain a letter for the recipient that certifies authority to receive the materials and states the license or permit number, issuing agency, expiration date,

types, forms, and quantities of materials authorized.

(3) **Confirmation.** Obtain written confirmation that materials shipped to VHA facilities were received at the intended destination. When receiving materials from VHA facilities, confirm receipt in writing. Report transfers of generally permitted or licensed material to non-VHA organizations according to instructions in the general license or permit.

i. **Transport of Radioactive Materials.** Applicable Regulations. VHA organizations shipping or transporting radioactive materials must follow NRC and DOT regulations found in 10 CFR Part 71 and 49 CFR Parts 172 and 173, respectively.

j. **Radioactive Wastes**

(1) **Management.** All radioactive materials and items contaminated with radioactive materials must be accounted for by inventory (see 4g(3)), pending disposal.

(2) **Security.** All radioactive waste materials must be secured against unauthorized access.

(3) **Local Policy.** Each VHA facility RSO shall prepare procedures for radioactive waste management, with consideration of local conditions, quantities and types of waste, and location and configuration of available storage.

k. **Reporting Incidents.** When an incident occurs, an MML permittee must ensure that actions immediately necessary to protect the safety of patients, staff, the public, and the environment take priority over reporting requirements.

(1) Incidents shall be reported to the VHA NHPP as described in this paragraph. The NHPP will ensure that all required reports are made to the NRC and other regulatory agencies. **NOTE:** *Exception: Incidents requiring immediate reports may be made directly to the NRC if NHPP personnel cannot be reached.*

(2) The following establishes criteria and procedures for reporting incidents involving radioactive materials to the NHPP (see App. D).

(a) **Reporting Immediately.** Report the following immediately by telephone, but no later than 3 hours following discovery:

1. Any event, such as fire, explosion, or toxic gas release that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of permitted material that could exceed regulatory limits.

2. Any event that causes or threatens to cause an individual to receive dose equivalents above limits listed in 10 CFR 20.2202(a)(1) Notification of Incidents, or the release of materials in excess of limits described in 10 CFR 20.2202(a)(2).

3. Receipt of a package or packages with external radiation levels or removable surface contamination that exceed the limits specified in 10 CFR 20.1906(d), Procedures for Receiving and Opening Packages.

4. Any lost, stolen, or missing radioactive materials in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR 20.

(b) Reporting no later than the next calendar day. Any medical misadministration, as defined in 10 CFR 35.2, must be reported by telephone no later than the next calendar day after discovery.

(c) Reporting within 24 hours. An incident report by telephone is required within 24 hours of discovery for the following:

1. Any event that causes or threatens to cause an individual to receive dose equivalents in excess of limits described in 10 CFR 20.2202(b)(1), or release of radioactive material as described in 10 CFR 20.2202 (b)(2).

2. Any unplanned contamination event that meets all of the following criteria:

a. Requires access to the contaminated area, by workers, or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry to the area.

b. Involves a quantity of radioactive material greater than five times the lowest annual limit of intake (ALI) in Appendix B to 10 CFR 20.1001 to 20.2401.

c. Requires restricting access to the area for a reason other than to allow radionuclides with a half-life of less than 24 hours to decay before decontamination.

3. Any event in which equipment is disabled or fails to function as designed when:

a. The equipment is required to be operational by regulation or conditions of a permit to prevent releases exceeding regulatory limits, or to prevent exposure to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

b. The equipment is required to be available and operable.

c. No redundant equipment is available and operable to perform the required safety function.

4. Any event requiring unplanned medical treatment at a medical facility of a person with spreadable radioactive contamination on the person's clothing or body.

5. An unplanned fire or explosion that damages any permitted radioactive material or any device, container, or equipment containing such material when:

a. The quantity of material exceeds five times the lowest ALI specified in Appendix B to 10 CFR 20.

b. The damage affects the integrity of the radioactive material or its container.

(d) Reporting within 5 Calendar Days. Whenever a leak test of a sealed source reveals the presence of 0.005 microcurie or more of removable contamination, a report must be filed within 5 calendar days. **NOTE:** *Leak testing is required by NRC regulations, MML permit conditions, or VHA regulations.*

(e) Reporting within 15 Calendar Days. A written report, containing the information listed in 10 CFR 35.33, shall be submitted within 15 days of discovery of a medical misadministration, as defined in 10 CFR 35.2.

(f) Reporting within 25 Calendar Days. Reports are required in writing within 25 calendar days of discovery for the following:

1. Lost, stolen, or missing radioactive material in a quantity greater than ten times the quantity in Appendix C to 10 CFR 20, that is still missing at the end of the 25 days.

2. Dose that exceeds the occupational dose limits specified in 10 CFR 20.1201, Occupational Dose Limits for Adults, or 10 CFR 20.1207, Occupational Dose Limits for Minor.

3. Dose that exceeds the limits for a embryo or fetus of a declared pregnant woman in 10 CFR 20.1208, Dose Limits to an Embryo or Fetus.

4. Dose to a member of the public that exceeds the limits in 10 CFR 20.1301, Dose Limits for Individual Member of the Public.

5. Dose that exceeds any applicable limit in the permit.

6. Doses in excess of the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

7. Levels of radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the facility permit.

8. Levels of radiation or concentrations of radioactive material in an unrestricted area in excess of ten times any applicable limit in 10 CFR Part 20, or in the facility permit even if persons were not exposed in excess of the limits in 10 CFR 20.1301.

(g) Reporting within 50 Calendar Days. Reports are required in writing within 50 calendar days of the discovery of defects or failures to comply as described in 10 CFR 21.21.

(h) Content of Telephone Reports. Telephone reports of incidents, including misadministrations, accidents, defects, or non-compliances, shall include to the extent that the information is available at the time:

1. Names of VHA organization and individual making the report, call-back telephone number, fax number, and mailing address.

2. Brief description of the incident, including date, time, and location.

3. Radionuclides, activities, and chemical and physical form of the material involved.

4. Any personnel exposure data available.

(i) Telephone Reports. All telephone reports shall be made to the appropriate NHPP Service Area office or to the NHPP RCPO Office.

1. During normal working hours (8:00 a.m. through 4:30 p.m.) call the RCPO at 501-257-1571.

2. Outside of normal working hours or if an NHPP staff member cannot be reached during normal working hours, call an NHPP telephone operator at (888) 887-0079 and ask the operator to page an NHPP staff member. Give the operator your name, a callback telephone number, and the facility name.

3. Telephonic reports must be made directly to a NHPP staff member; it is not sufficient to leave a recorded message.

(j) Content of Written Reports. Reports submitted in writing shall include:

1. Name of VHA organization and individual making the report, telephone number, fax number, and mailing address.

2. Description of event, including probable cause(s).

3. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

4. The exact location of the event.

5. Date and time of the event.

6. Radionuclides, activities, and chemical and physical form of the material involved.

7. Corrective actions taken or planned, estimated completion time, and expected results.

8. Measures or estimates of surface contamination.

9. Measures or estimates of radiation levels.

10. Measures or estimates of air and/or water release.

11. Extent of exposure of persons to radiation or radioactive material.
12. An assessment of exposures and risks to all other facilities, locations and persons.
13. Other VHA, Federal, state or local organizations or agencies notified.
14. VHA Radioactive Materials Permit Number.
15. For reports of medical misadministrations, all information listed in 10 CFR 35.33.

(k) Written Reports. All written reports shall be submitted to:

National Health Physics Program (115HP)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

(l) Miscellaneous. If there is doubt whether a report is required regarding an incident, report it. MML permittees are encouraged to notify the NHPP of incidents sooner, whenever possible, than the previously listed time limits. **NOTE:** *MML permittees are requested to send written reports of incidents either by overnight mail or to fax a copy.*

1. **Response to Incidents Involving Radioactive Materials.** Facility staff is responsible for initial response to, investigations of, and reports on incidents involving radioactive materials.

(1) **Response.** The initial response to incidents at VHA facilities is the responsibility of the facility staff. Each permittee must have a mechanism for notifying, both during and outside of normal working hours, their RSO, radiation safety staff, and/or other qualified individuals, e.g., Chairperson, RSC or nuclear medicine physician, commensurate with the scope of radioactive material use and for responding promptly to incidents. Each permittee shall train facility personnel, or designated backup personnel, in working with radioactive material in taking precautions to prevent incidents.

(2) **Assistance from NHPP.** Assistance of the NHPP may be requested at any time, and assistance regarded as necessary for these purposes will be provided. This assistance may include technical guidance, medical advice, on-site personnel assistance, and equipment.

(3) **Investigations.** Investigation of incidents is primarily the responsibility of the facility RSO. Reactive inspections may be conducted by the NHPP to identify causes of the incident; to evaluate the adequacy of response and corrective actions; and to identify violations of NRC regulations, MML license conditions, VHA regulations, and MML permit conditions. When a reactive inspection is not performed, an NHPP inspector will review the incident and the facility's response during the next routine inspection.

(4) **Reports.** Incident reports are sent to NHPP; following review, the NRSC determines when an investigation is complete.

m. **Termination of Permits.** Permit holders must follow the applicable requirements of 10 CFR 30, 40, and 70, when planning for permit termination and subsequent site decommissioning. Permit holders must notify the NRSC through the RCPO in the event of permit termination and site decommissioning according to the notification timelines contained in 10 CFR 30.36. The RCPO will use IMC 2605 and Nuclear Material Safety and Safeguards (NMSS) Decommissioning Handbook guidance to determine the appropriate decommissioning category, and make necessary NRC notifications.

(1) **Decommission Plan.** If a decommissioning plan is required, one must be prepared for NHPP and/or NRC approval according to applicable portions of the NMSS Decommissioning Handbook. NHPP must submit all Type IV decommissioning plans to NRC for review and must notify NRC of all Type III decommissioning.

(2) **Decommissioning.** Upon NHPP or NRC approval, execute the decommissioning plan disposing of all radioactive sources, contaminated materials, and waste.

(3) **Documentation.** Submit the following termination documents to NHPP:

(a) Completed NRC Form 314, Certificate of Disposition of Materials.

(b) Copy of all receipts confirming that materials were received by another permittee, an NRC or Agreement State Licensee, or shipped to a licensed broker for final disposition.

(c) The decommissioning report that includes a radiation survey documentation showing no radioactive materials or residual contamination in use or storage areas in excess of the limits for unrestricted release in 10 CFR Part 20.

n. **Record Retention.** Records pertaining to the MML shall be retained and stored according to the requirements of 10 CFR.

5. REFERENCES

a. Title 5 U.S.C. Section 552a (Privacy Act of 1974).

b. Title 42 U.S.C. Section 2011 et seq. (Atomic Energy Act (AEA) of 1954).

c. Title 42 U.S.C. Section 5801 et seq. (Energy Reorganization Act of 1974).

d. Title 42 U.S.C. Section 6901 et. seq. (Resource Conservation and Recovery Act (RCRA)).

e. Title 10, Code of Federal Regulations (CFR), Energy:

Part 2, Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders,
Part 19, Notices, Instructions and reports to Workers: Inspection and Investigations,
Part 20, Standards for Protection Against Radiation,
Part 21, Reporting of Defects and Noncompliance,
Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material,
Part 31, General Domestic Licenses for Byproduct Material,

Part 33, Specific Domestic Licenses of Broad Scope for Byproduct Material,
Part 34, Licenses for Radiography and Radiation safety Requirements for Radiographic
Operations,
Part 35, Medical Use of Byproduct Material,
Part 36, Licenses and Radiation Safety for Irradiators,
Part 40, Domestic Licensing of Source Material,
Part 70, Domestic Licensing of Special Nuclear Material,
Part 71, Packaging and Transportation of Radioactive Material,
Part 110, Export and Import of Nuclear Equipment and Material, and
Part 150, Exemptions and Continued Regulatory Authority in Agreement States.

f. Title 29 CFR, Labor.

g. Title 40 CFR, Protection Of Environment.

h. Title 49 CFR, Transportation.

DEFINITIONS

1. **Accelerator Produced Radioactive Material.** Radioactive material produced as the result of operating a particle accelerator.
2. **Agreement State.** Any state, territory, or possession of the United States that, by agreement with the Nuclear Regulatory Commission (NRC), has assumed regulatory authority over byproduct, source, and certain small quantities of special nuclear material.
3. **Associate Radiation Safety Officer (RSO).** A person, named as such on the Veterans Health Administration (VHA) Radioactive Material Permit, who is qualified to act as RSO when the primary RSO is absent. Unless otherwise requested by the permittee, the alternate RSO becomes the primary RSO when the named primary RSO leaves the organization.
4. **Assistant Radiation Safety Officer.** A person in training for the position of RSO, who may only act under the supervision of the RSO.
5. **As Low As Reasonably Achievable (ALARA).** The principle that personnel exposures must be maintained as low as possible consistent with existing technology, cost, and operational requirements.
6. **Byproduct Material.** Radioactive material (except Source and Special Nuclear Material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using Source or Special Nuclear Material. *NOTE: Byproduct material, source material, and special nuclear material are defined in Title 10 Code of Federal regulations (CFR) 20.*
7. **Committee.** The VHA National Radiation Safety Committee (NRSC).
8. **Diagnostic Clinical Procedures Manual.** A collection of written procedures that describes each method (and other instructions and precautions) used to perform diagnostic clinical procedures, where each diagnostic clinical procedure is approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.
9. **Exclusive Federal Jurisdiction.** Property under the exclusive control or ownership of the federal government that has been ceded legislative power by the state or has had such power reserved from grants to the states.
10. **Human Use.** The internal administration of radioactive materials, or the external administration of ionizing radiation from radioactive materials, to humans.
11. **Incident.** For this Handbook, an incident is an undesirable event involving radioactive material such as a fire or explosion involving radioactive material, a loss or theft of radioactive material, a spill of radioactive material, a release of radioactive material that exceeds permissible limits, a radiation exposure of personnel that exceeds permissible limits, the contamination of

personnel with radioactive material, or a medical misadministration defined in 10 CFR 35.2. The term incident includes any event that must be reported to the NRC pursuant to 10 CFR 20.1906(d), 20.2201, 20.2202, 20.2203, 21.21, 30.9(b), 30.50, 35.33, and 35.59.

12. License. Written authorization from the NRC or an Agreement State to receive, possess, use, or transfer Byproduct, Source, or Special Nuclear Material. Written authorization from a State to receive, possess, use, or transfer naturally occurring radioactive material or accelerator-produced radioactive material.

13. General License. A license, published in NRC or Agreement State Regulations, that is effective without any need to send an application to the NRC or an Agreement State.

14. Specific License. A license issued by the NRC or Agreement State to a named applicant who has filed an application authorizing acquisition, ownership, receipt, storage, use, transfer, and disposal of chemical or physical forms of radioisotopes specified in the license. This license has an expiration date renewable on application to the issuing authority. The license may be limited in scope (authorizing only certain specific radioisotopes for limited users) or broad (authorizing the use of a wide variety of radioisotopes without regard to form, quantity, or use).

15. Licensed Material. Radioactive material possessed under the auspices of the VHA's NRC Master Materials License (MML). This includes byproduct material and any source material and special nuclear material possessed under the MML. Licensed material does not include accelerator-produced radioactive material, nor does it include naturally occurring radioactive material that is neither source material nor special nuclear material.

16. Low-Level Radioactive Waste (LLRW). Radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or Byproduct Material as defined in Section 11e(2) of the Atomic Energy Act of 1954 (AEA-54), i.e., uranium or thorium tailings and waste.

17. Misadministration. For this Handbook, misadministration is administration to humans of:

a. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 involving the wrong patient or wrong radiopharmaceutical, or when both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

b. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or when the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

c. A gamma stereotactic radiosurgery radiation dose involving the wrong patient or wrong treatment site; or when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.

d. Teletherapy Radiation Dose

(1) A teletherapy radiation dose involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(3) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

e. Brachytherapy Radiation Dose

(1) A brachytherapy radiation dose involving the wrong patient, wrong radioisotope, or wrong treatment site **NOTE:** *excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site;* or

(2) Involving a sealed source that is leaking when, for a temporary implant, one or more sealed sources are not removed on completion of the procedure; or

(3) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

f. Diagnostic Radiopharmaceutical Dosage

(1) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or

(2) When the administered dosage differs from the prescribed dosage and when the dose to the patient exceeds five rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

18. Mixed LLRW (Mixed LLRW). Low-level radiological wastes that also contain chemical constituents that the Environmental Protection Agency (EPA) defines as hazardous in 40 CFR 261, Identification and Listing of Hazardous Waste.

19. Naturally Occurring Radioactive Material. Radioactive material that occurs in nature; that is, carbon-14, radium-226, thorium-232, uranium-238, etc.

20. Nuclear Reactor. A facility using fissile materials in a self-supporting chain reaction

(nuclear fission) to produce heat or radiation for both practical application and research and development.

21. Nuclear Regulatory Commission. An agency established by Title II of the Energy Reorganization Act of 1974 (Public Law 93-438) to regulate Byproduct, Source, and Special Nuclear Material as provided for by the AEA-54, as amended. Within the NRC, final authority rests with the five member Commission acting as a body.

22. Particle Accelerator. A device that accelerates charged particles to produce a beam of high energy radiation or to produce radioisotopes.

23. Permit. A VHA radioactive material permit issued to a facility under the authority of an MML.

24. Prescribed Dosage. The quantity of radiopharmaceutical activity as documented in a written directive or either in the diagnostic clinical procedures manual or in any proper record according to the directions of the authorized user for diagnostic procedures. ***NOTE:** A written directive is an order in writing for a specific patient, dated and signed by an authorized user before the administration of a radiopharmaceutical or radiation.*

25. Prescribed Dose For:

- a. **Gamma stereotactic radiosurgery.** The total dose as documented in the written directive.
- b. **Teletherapy.** The total dose and dose per fraction as documented in the written directive.
- c. **Brachytherapy.** Either the total source strength and exposure time or the total dose, as documented in the written directive.

26. Radiation Safety Officer (RSO). An individual with specific education and professional experience in radiation protection practice appointed by a VHA facility director and approved by the VHA Radiation Safety Committee to manage radiation safety programs. ***NOTE:** The term "Radiation Safety Officer" is a functional title and does not denote an occupational code. An RSO should be the most technically qualified person available. The RSO must have the education and professional experience needed for the position.*

27. Radioactive Material. Materials whose nuclei, because of their unstable nature, decay by emission of ionizing radiation. The radiation emitted may be alpha or beta particles, gamma or X-rays, or neutrons.

28. Recordable Event. The administration of any of the following:

- a. A radiopharmaceutical or radiation without the written directive where a written directive is required.
- b. A radiopharmaceutical dosage or radiation dose where a written directive is required

without daily recording of each administered radiopharmaceutical dosage or radiation dose in the proper record.

c. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 15 microcuries.

d. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage.

e. A teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

f. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

29. Restricted Area. An area or room posted to limit access for protection of individuals against undue risks from radiation and radioactive material. **NOTE:** *Restricted areas do not include areas within a posted room that is designated for residential use or as a non-radioactive materials use area.*

30. Source Material. Uranium or thorium or any combination thereof in any physical or chemical form; or ores that have, by weight, one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Source Material does not include Special Nuclear Material.

31. Special Nuclear Material. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235; any other material that the NRC determines to be Special Nuclear Material, and any material artificially enriched by the foregoing. Special Nuclear Material does not include Source Material.

32. Unrestricted Area. An unrestricted area is any area that is not a restricted area (as restricted area is defined in this directive).

33. User. For this Handbook, a user is:

a. An organization authorized by a VHA Radioactive Material Permit to have and use radioactive materials, or

b. A person specifically named on a VHA Radioactive Material Permit as authorized to handle or to supervise handling radioactive materials listed on the permit.

c. A person named in a permit condition by a radiation safety committee with local approval

authority to handle or supervise the handling of radioactive materials listed on the permit.

34. VHA MML. The single NRC license issued to the Department of Veterans Affairs (VA) delegating to the VHA regulatory authority over Byproduct and Source materials used by the VHA.

35. VHA Radioactive Material Permit. Written authorization from the VHA Radiation Safety Committee for VHA organizations to receive, possess, distribute, use, transfer, or dispose of radioactive materials. Permits parallel NRC licenses in applications and scope. Unlike the NRC, a single permit may authorize Byproduct, Source, Special Nuclear Material, Accelerator Produced Radioactive Material, and Naturally Occurring Radioactive Material.

36. VHA National Radiation Safety Committee (NRSC). A committee set up according to the VHA MML to coordinate the administrative and regulatory aspects of permitting, possessing, distributing, using, transferring, transporting, and disposing of all radioactive materials in the VHA facilities.

37. Written Directive. An order in writing for a specific patient, dated and signed by an authorized user before the administration of a radiopharmaceutical or radiation that has this information:

a. **For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.** The dosage.

b. **For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131.** The radiopharmaceutical, dosage, and route of administration.

c. **For gamma stereotactic radiosurgery.** Target coordinates, collimator size plug pattern, and total dose.

d. **For teletherapy.** The total dose, the dose per fraction, treatment site, and overall treatment period.

e. **For high-dose-rate remote afterloading brachytherapy.** The radioisotope, treatment site, and total dose.

f. **For all other brachytherapy.** Before implantation, the radioisotope, number of sources, and source strengths, and after implantation, but before completion of the procedure, the radioisotope, treatment site, and total source, strength, and exposure time (or, equivalently, the total dose).

EXEMPT QUANTITIES

These exemptions apply to accelerator produced and naturally occurring radioisotopes and are in addition to those in Title 10 Code of Federal Regulations (CFR) 30.71, Schedule B.

<u>RADIONUCLIDE</u>	<u>MICROCURI</u>
Beryllium-7	0.1
Cesium-129	100
Cobalt-57	100
Gallium-6a through 6f	100
Gold-19	10
Germanium-68	10
Indium-111	100
Iodine-123	100
Iron-52	10
Potassium-43	10
Radium-226	0.01
Rubidium-81	10
Sodium-22	10
Xenon-127	100
Yttrium-87	10

NOTE: *These exemptions do not apply to radioactive material in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.*

**MINIMUM TRAINING AND EXPERIENCE REQUIRED FOR A
RADIATION SAFETY OFFICER (RSO)**

1. **Byproduct Material for In Vitro Testing by Title 10 Code of Federal Regulations (CFR) 31.11.** RSOs must have formal training as physicians, veterinarians, clinical laboratory officers, or superintendents.
2. **Cobalt-57 in Less than 10 Microcuries Per Kit for In Vitro Testing.** RSOs must have formal training as physicians, veterinarians, or clinical laboratory officers or superintendents.
3. **Self-contained Irradiators.** RSOs must have additional specialized safe operation training provided by the irradiator manufacturer.
4. **Generally Licensed Devices.** Use of generally licensed devices shall be in accordance with 10 CFR 31.5.
5. **Source Material.** RSOs must have training and experience as detailed in 10 CFR 35.900.
6. **Medical Permit Authorizing Medical Use of Radioactive Materials for Diagnosis or Therapy.** For RSO requirements, see 10 CFR 35.900, Radiation Safety Officer.
7. **Type C Permit of Broad Scope.** RSOs must have:
 - a. A college degree at the bachelor level or equivalent training and experience in the physical or biological sciences or engineering.
 - b. Forty hours of formal RSO training, including instruction in the safe handling of radioactive material, characteristics of ionizing radiation, units of radiation dose and quantity, radiation detection and instrumentation, biological hazards of exposure to radiation, regulatory requirements of the Nuclear Regulatory Commission (NRC) for radioactive material including accounting, reporting, using, transferring, shipping and disposing of radioactive materials that the RSO will use on the job.
 - c. Six months to 1 year of prior experience with radioactive materials and devices. Professional experience may include managing and administering a radiation safety program related to the types, quantities, and uses of the radioactive materials requested for use. Prior experience as a named license or permit RSO is desirable.
 - d. The National Health Physics Program (NHPP) reviews qualifications, including past performance on other licenses or permits. The review may include an interview of the applicant RSO.

8. Type B Permit of Broad Scope. RSOs must have:

a. A college degree at the bachelor level or equivalent training and experience in the physical or biological sciences or engineering.

b. Forty hours of formal RSO training including instruction in the regulatory requirements of the NRC as outlined in subparagraph 7b. Additional formal training in radiation safety management, radiation dose assessment, and emergency response is desirable.

c. Two to 3 years prior experience with radioactive material and devices. Professional experience must include managing and administering a radiation safety program related to the types, quantities, and uses of the radioactive materials that the applicant would use on the job. Prior experience as a named license or permit RSO is required.

d. NHPP reviews qualifications, including the applicant RSO's past performance on other licenses or permits. The review may include an interview of the RSO.

9. Type A Permit of Broad Scope. RSO must have:

a. A college degree at the bachelor level or equivalent training and experience in the physical or biological sciences or in engineering.

b. Forty hours of formal RSO training, including instruction in the regulatory requirements of the NRC as outlined in subparagraph 8b. Additional formal training in radiation safety management, radiation dose assessment, and emergency response is desirable.

c. Five years prior experience with radioactive material and devices. Professional experience must include the management and administrative requirements in subparagraph 8c. Prior experience as a named license or permit RSO is required.

d. The NHPP reviews qualifications, including the applicant RSO's past performance on other licenses or permits. The review may include an interview with the RSO.

INCIDENT REPORTS

1. **Telephonic Reports.** Telephonic reports of incidents, made pursuant to subparagraph 4k(2)(h) of VHA Handbook 1105.1, shall include, to the extent that the information is available at the time:

a. Names of Veterans Health Administration (VHA) organization and individual making the report, call-back telephone number, fax number and mailing address.

b. Brief description of the incident, including date, time, and location.

c. Radionuclides, activities, and chemical and physical form of the material involved.

d. Any personnel exposure data available.

2. **Content of Written Reports.** Reports submitted in writing, pursuant to subparagraph 4k(2)(j) of the VHA Handbook 1105.1, shall include:

a. Name of VHA organization and individual making the report, telephone number, fax number, and mailing address.

b. Description of event, including probable cause(s).

c. The manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

d. The exact location of the event.

e. Date and time of the event.

f. Radionuclides, activities, and chemical and physical form of the material involved.

g. Corrective actions taken or planned, estimated completion time, and expected results.

h. Measures or estimates of surface contamination.

i. Measures or estimates of radiation levels.

j. Measures or estimates of air and/or water releases.

k. Extent of exposure of persons to radiation or radioactive material.

l. An assessment of exposures and risks to all other facilities, locations and persons.

- m. Other VHA, Federal, state, or local organizations or agencies notified.
- n. VHA Radioactive Materials Permit Number.
- o. For reports of medical misadministrations, all information listed in Title 10 Code of Federal regulations (CFR) 35.33.